Claim Rejections, first paragraph

Claim 1-17 are rejected under 35 U.S.C. 112, first paragraph, as not providing enablement. The applicant respectfully disagrees. The Examiner admits that the specification is enabling for an inhibitor comprising (a) first moiety operably linked to (b) a second moiety. In Thrope et al. no undue experimentation was necessary to create the hybrid molecules, supporting applicant's argument against rejection (see below).

The state of the prior art

Thrope et al. teach a composition comprising a bispecific antibody and a coagulant for tumor regression. Thrope et al. does not teach an inhibitor, which is deactivatable by a reagent produced by a target cell. D'Amico et al. teach making a drug complex comprising peptide attached with a drug through another small peptide linker, which is cleavable by PSA and the liberated drug is an inhibitor as it inhibits growth of prostate cancer cells. The complex of peptide attached with a drug through another small peptide linker is not an inhibitor since it does not inhibit growth of prostate cancer cells because it is inactive. The cleavage activates the inhibitor. D'Amico et al. teach opposite of the instant invention that claims "An inhibitor, which is deactivatable by a reagent produced by a target cell ". Mhaka et al. teach making an inhibitor for prostate cancer by attaching 5-fluorodeoxyuridine to a peptide sequence cleavable by PSA – creating a prodrug. When the peptide is cleaved, the liberated drug is activated and inhibits proliferation of cancer cells. Again, the prodrug is activated by the cleavage. Mhaka et al. do not teach an inhibitor, which is deactivatable by a reagent produced by a target cell. Mhaka et al. teach the opposite of the instant invention. Gillies et al. teach making a fusion of IL-2 and Fc receptor. Gillies et al. teach that proteins can be joined together through either chemical or genetic manipulation using methods known in the art. Gillies et al. do not teach "An inhibitor, which is deactivatable by a reagent produced by a target cell ".

Amount of guidance

The disclosure of the instant invention and disclosed examples all teach an inhibitor, which is deactivatable by a reagent produced by a target cell ie. a first moiety operably linked to a second moiety when the second moiety is specifically cleaved by a reagent produced by a target cell, wherein said first and second moieties are not attached in nature and wherein specific cleavage of said second moiety causes reduction of binding, inhibiting, suppressing, or neutralizing activity of said inhibitor. Only a routine experimentation is required to test for reduction in binding, just like testing monoclonal antibodies for binding to their intended targets. As the Examiner admits (p. 13) "The person of ordinary skills in the art would have been motivated to make an inhibitor for tissue specific targeted delivery … one would have a reasonable expectation of success in making an inhibitor …". One skilled in the art would certainly know how to select for the desired molecule and, therefore, know how to practice the instant invention.

Quantity of experimentation

As explained above, extensive guidance and direction in the disclosure of the present invention and several disclosed working examples, the state of prior art – disclosing inhibitors activated by cleavage by a reagent produced by target cell, the predictability of desired outcomes to those skilled in the art and only routine experimentation required to obtain desired molecules all constitute perfect enablement of the present invention. It is just like with selection of monoclonal antibodies, only a routine selection is required to select for a desired inhibitor, which is deactivatable by a reagent produced by a target cell. Such selection doesn't amount to an undue experimentation but merely to a routine one. Presented working examples demonstrate that only a routine experimentation is needed to generate desired fusion molecules.

Claim Rejections, 35USC 102

For an unknown reasons, the Examiner interprets claim: 1. that clearly states "An inhibitor which is deactivatable by a reagent produced by a target cell ..." as "any inhibitor that can be deactivated by any reagent produced by a target cell". Such interpretation changes meaning of claims as filed. To further specify the reagent of claim 1, claim 5. states "The inhibitor of claim 1, wherein said active agent is selected from the group consisting of ....". Claims 1-5, 7-9, 11 and 13-17 are rejected as anticipated by Thrope et al. Again, the Examiner requests the restriction requirement then makes the requirement final and then uses the non-elected species for further examination of the instant application. Claim 1 specifically states that: a second moiety is specifically cleavable by a reagent produced by a target cell, therefore, the claims claim opposite than Thrope et al. that teach a non-specific cleavage by a protease. Thrope et al. explicitly or implicitly anticipate the opposite than disclosed and claimed in the instant invention. Obviously, in Thrope et al. no undue experimentation was necessary to create the hybrid molecules patented, supporting applicant's argument against rejection under 35 U.S.C. 112, first paragraph (see above).

Claim Rejections, 35 USC 103

Claims 10 and 12 are rejected under 35 USC 103(a) as being unpatentable as being obvious. Thrope et al., Mhaka et al., D'Amico et al. teach the opposite to the claim invention, they do not teach an inhibitor, which is deactivatable by a reagent produced by a target cell (see above). It is not obvious that making and using the opposite of Thrope et al., Mhaka et al., D'Amico et al. combined teaching would work and be useful for anything let alone for difficult task such as cancer treatment. The fact that the instant invention is not obvious is further supported by the fact that the deactivatable inhibitor idea as claimed has not been patented, published or reduced to practice before the instant invention.

Conclusion

It is believed that all of the stated requirements have been met. Applicant respectfully requests that the Examiner gives due consideration to the allowability of pending Claims, which are believed to recite subject matter that is patentable. An early action allowing the pending Claims is cordially solicited.

AUTHORIZATION

If further extension of time is necessary to prevent abandonment of this application, then such extension of time are hereby petitioned under 37 CFR 1.136(a).

Respectfully submitted,

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